March 21, 2014

Expert Report of Shelby F. Thames, Ph.D.

Prepared for In re: The Matter of Ethicon, Inc.
Pelvic Repair System Products Liability Litigation
Jo Huskey (2:12-cv-05201) vs. Ethicon *et al.*
Tonya Edwards (2:12-cv-09972) vs. Ethicon *et al.*

All of my opinions herein are stated to a reasonable degree of scientific/professional certainty and probability.

I have been asked to do the following:

- Address the issues of polypropylene (PP) as a material for use in the human body, its suitability for *in vivo* use considering its chemical and physical properties, propensity for degradation, material strength and viability, as well as longevity.
- Determine whether Ethicon appropriately tested laser cutting versus mechanical cutting of the mesh.
- Determine if laser cutting compromises the integrity of the mesh.

A copy of my Curriculum Vitae is attached as Appendix A. A list of the cases in which I have testified within the past four years is attached as Appendix B, and the materials I reviewed and/or relied upon in connection with the preparation of this report are listed in Appendix C. I am being compensated for my work in this matter at a rate of $375.00/hour.

Ethicon's TVT device made from PP is suitable for its intended use. Polypropylene has been used in medical devices for decades, and for good reason.[1,2,3] It is a polymeric species of the propylene monomer and is a durable, thermoplastic polymer composed of carbon and hydrogen. PP offers mechanical properties of durability and elasticity and is the lightest major plastic with a density of 0.905 g/ml and the crystallizability of isotactic polypropylene makes it the polymer of choice for properties of commercial interest.[4,5]

The monomer propylene ($CH_2{=}CH{-}CH_3$) shown in Figure 1 when polymerized, gives polypropylene; a polymeric species (many monomers) where many monomers are attached through carbon to carbon bonds, Figure 2.[6] The process of combining monomers together to form larger molecules is termed polymerization. Stated differently, a polypropylene polymer is a chain of propylene monomers linked together. Changes in process conditions and catalyst can lead to production of three configurations of polypropylene, and in the current instance isotactic PP (iPP). The isotactic form of PP possesses the configuration wherein the side-chain, or pendant -CH_3 (methyl) groups are aligned on the same loci of each tetrahedral carbon atom

Tonya Edwards Explant Analysis

I have been unable to physically and chemically examine the Tonya Edwards explant due to the destructive and compromising methodology used by plaintiff's representatives in handling the sample(s). There was no explant distribution or sample splitting made available to the defendants. The entire sample was maintained by plaintiff's counsel and their experts. The explant sample(s) has been physically and chemically altered irreversibly in such a way that prohibits me from observing, testing, and evaluating the explant in its condition and state at explantation. Accordingly, I cannot not reach reliable, scientifically valid conclusions via attempting to evaluate the explant in its present state.

The Prolene explant, a hydrocarbon iPP mesh explanted from Ms. Edwards, was immediately placed in formalin, after surgical removal, for fixation and preservation. The explanted mesh remained in this state for several months at which time it was delivered by Plaintiff's attorneys to Dr. Vladimir Iakovlev, a pathologist.

Dr. Iakovlev retained the explant from approximately May 2013 to February 28, 2014 at which time its parts were received by defendant's experts. Dr. Iakovlev apparently embedded the entirety of the mesh in two paraffin blocks and sectioned each block. Consequently, there was no un-adulterated or otherwise "pristine explant" to provide defendant's experts for evaluation. I was able to view the explant as noted in Figure 13 a) and b) below which shows the paraffin encased explant blocks along with slides sectioned from the paraffin blocks. Moreover, the mesh was, in its entirety, covered with paraffin, a hydrocarbon wax, melting at approximately 56 °C (133 °F).

- It is my opinion that the LC/MS analytical data presented in the Jordi Report is unreliable in establishing the concentration/efficacy of Ethicon's antioxidants and should be disregarded in its entirety.
- LC and MC are acceptable cutting techniques for Ethicon PP mesh devices. The testing of LC v. MC was adequate, well documented, and was performed appropriately. LC does not adversely affect the performance and properties of PP device(s).
- I have not seen definitive FTIR data from the work of Ethicon, the Jordi reports, or my work confirming oxidation or degradation of Ethicon's iPP.
- The Jordi report also mentions 24 explant samples evaluated. I do not know how the explants were selected, from what pool of people, the selection method or general condition of the explants when they were received by the plaintiff's experts. Accordingly, I am prohibited from reaching valid, scientific conclusions.
- Because no explant was available in the Huskey litigation, I cannot render scientific opinions as to its condition.
- I am prohibited from providing any reliable, scientific opinions regarding the condition of the Edwards explant due to the condition and destructive testing of the explant by the plaintiffs' experts prior to our receipt of same.

I reserve the right to supplement this report and analysis, create additional exhibits as necessary to illustrate my testimony based upon the receipt of additional information, documents and materials, and to revise this report following the receipt of additional information and/or materials that have not yet been made available, as well as the availability of any additional eye witnesses to the incident and the events that occurred immediately thereafter.

Shelby F. Thames, Ph. D.

Instrumentation

FTIR